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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,931	12/31/2003	Dilip G. Saoji	U 013963-9	6678

140 7590 07/13/2007

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EXAMINER
PESELEV, ELLI

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,931	SAOJI ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-66 and 68-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-66 and 68-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-66 and 68-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (U.S. Patent No. 4,552,879) and de Souza et al (U.S. Patent No. 6,514,986) in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. patent No. 5,824,668).

Ishikawa et al disclose a composition comprising the claimed compound (column 25, lines 65-68 and column 26, lines 1-25) but do not disclose said compound in combination with an amino acid or cyclodextrin. However, since Ishibashi et al disclose that cyclodextrins and amino acids are well known solubilizing agents (column 11, lines 31-34) and Rubinfeld et al disclose a conventional use of cyclodextrins as solubilizing agents (column 2, lines 26-67, columns 3-4 and column 10, lines 27-40), a person

having ordinary skill in the art at the time the claimed invention was made would have been motivated to combine a compound disclosed by Ishikawa et al with a cyclodextrin or an amino acid in order to improve solubility of said compound.

Applicant's arguments filed June 7, 2007 have been fully considered but they are not persuasive.

Applicant contends that Ishikawa et al disclose the use of sodium salt of the compound and glucose in distilled water. Applicant further contends that the use of sodium salt causes severe phlebitis and said composition cannot be used. However, sine sodium salt cannot be used, it provides motivation to a person having ordinary skill in the art at the time the claimed invention was made make said compound soluble in the absence of sodium salt. Further, note that Ishikawa et al also disclose pharmaceutical compositions comprising an active compound in combination with ordinary dissolving aids (column 44, lines 24-40). Thus Ishikawa et al provide further motivation to combine the active compound with a solubilizing agent.

Applicant also contends that De Souza et al do not disclose any pharmaceutical composition of arginine salt of the compound, as a solution using a solubilizing agent. This argument has not been found persuasive since De Souza et al in column 8, lines 34-48, disclose that liquid pharmaceutical formulations which comprise the argentine salt of the invention. A person having ordinary skill in the art at the time the claimed invention was made would have been motivated to add a conventional solibilizing agent to the liquid composition disclosed by de Souza et al in order to improve the solubility of the active agent.

Applicant contends that the disclosure of solubilizing agents cyclodextrin and arginine by Ishibashi et al relates to solid compositions. However, this does not detract from the fact that arginine and cyclodextrin were known as solubilizing agents at the time the claimed invention was made. Further, note that applicant admits on page 8 of the specification that formulations of various drugs with various cyclodextrins have been proposed in literature.

A person having ordinary skill in the art at the time the claimed invention was made would have been motivated to combine a known drug with a know solubilizing agent in order to improve solubility of said drug. Therefore, the claimed compositions, methods and process are still deemed prima facie obvious over the cited prior art.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-66 and 68-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 1, 18, 29 and 30 of U.S. Patent No. 6,514,986 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668). The claims of U.S. Patent read on compositions comprising the claimed compound but not in the combination with a solubilizing agent. However, since amino acids and cyclodextrins were well known in the art as solubilizing agents as disclosed by Ishibashi et al (column 11, lines 31-34) and Rubinfield et al (columns 2-4 and 10), a person having ordinary skill in the art at the time of the claimed invention would have been motivated to add amino acid or a cyclodextrin to the patented compositions in order to improve the solubility of the patented compound.

Claims 45-66 and 68-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,608,078 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668). The patented claims read on compositions comprising the claimed compound but not in combination with a solubilizing agent. However, since each of Ishibashi et al and Rubinfeld et al disclose the conventional use of solubilizing agents as described above, the claimed compositions are prima facie obvious over the patented compositions.

Claims 45-66 and 68-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8-111 of U.S. Patent

No. 6,664,267 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668) for the same reasons as set forth above.

Claims 45-66 and 68-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-10 of U.S. Patent No. 6,750,224 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668) for the same reasons as set forth above.

Claims 45-66 and 68-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 7, 21-23, 29-38 and 45-47 of copending Application No. 09/566,875 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668) for the same reasons as set forth above.

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments filed June 7, 2007 have been fully considered but they are not persuasive.

Since the applicant has failed to address the above stated obviousness-type double patenting rejections, said rejections have not been overcome.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

ELLI PESELEV
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GROUP 1200